and humanistic) requirements to support reimbursement and prescription of biosimilar drugs in three Asian markets (Japan, South Korea and China). **METHODS:** We conducted secondary research to review the macroeconomic factors impacting biosimilar entry (regulatory policy, intellectual property protection etc.) Payer/physician guidance and positions on biosimilar use across markets and diseases were also reviewed. Following this, primary research was conducted with a mix of payers and physician stakeholders to understand: 1. The therapy areas that payers/physicians consider most attractive for biosimilars; 2. Payer/physician value drivers and evidence requirements (bioequivalence, comparative data etc.) across therapy areas that would support public reimbursement and prescription. 3. Expectations around price differentials vs. branded biologics and the implications these differentials have on access and utilization of biosimilars. **RESULTS:** Evidence requirements vary by market, with Japan and S.Korea being fairly consistent while China having lower thresholds. Evidence requirements also tend to vary by therapy area and complexity of the biologic. Overall, efficacy/ safety data and price are key value drivers for biosimilar reimbursement and uptake. In the absence of comparative data vs. the branded biologic, concerns around safety/efficacy may impact uptake but the promise of significant budget savings supports positive reimbursement/ access decisions. **CONCLUSIONS:** The access environments for biosimilars in the developed markets of Japan and S.Korea can be expected to be similar to other developed markets across the world. However, China is likely to be more favourable than the developed markets when it comes to access and uptake of biosimilars.

PMS30

CLOSING THE GAP: REDUCED DELAY TO DRUG MARKETING APPROVAL BETWEEN THE WEST AND ASIA

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OBJECTIVES: Historically, there has been a delay between the marketing approval of drugs in Western countries and other markets worldwide. However, the pharmaceutical market in Asia is rapidly expanding (a projected increase in global market share of 7% from 2000–2016). The objective of this analysis was to investigate patterns of drug approvals in Western and Asian countries. **METHODS:** National English-language drug regulatory authority websites were searched for drug approval dates in key Western (United States and European Union) and Asian countries (Japan, Hong Kong, Indonesia and Singapore) in type 2 diabetes mellitus (T2DM) and rheumatoid arthritis (RA). For drugs with ≥1 approval in each region, we analysed how the delay in average approval date between the West and Asia changed over time. **RESULTS:** At least 1 West and 1 Asian approval was recorded for 21 drugs (T2DM n=12, RA n=9), out of the 31 included. The delay between approval in the West and Asia was found to decrease between 2000 and 2014 in both T2DM and RA, and there was an overall strong negative correlation between the date of first approval and the delay ($p<0.0001$; Spearman Rank correlation). Despite the delay for RA drugs (mainly biologics) being over double that of the T2DM (all small molecules) in 2000 (8.6 vs 3.6 years), by 2009 the delay for drugs in both indications was less than 2 years, due to a greater rate of decrease in delay for RA. **CONCLUSIONS:** Whilst the current analysis has limitations, it is clear that the delay in date of approval of T2DM and RA drugs in Western and APAC countries has decreased dramatically over the past decade. This may have an impact on the future marketing strategies of pharmaceutical companies. Further analysis would be needed to ascertain if this same trend is observed in other emerging markets.

PMS31

HEALTH LITERACY AND HEALTH CARE UTILIZATION AMONG ADULTS WITH OSTEOPOROSIS

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OBJECTIVES: Every year, osteoporosis accounts for two million fragility fractures leading to disability, decreased quality of life and increased health care cost. Health literacy poses a challenge in delivering effective health care services. Impact of health literacy on health care utilization in the osteoporotic patients is unknown. We describe(1) health care utilization for osteoporosis patients in the USA(2) their prescription drug expenses, and(3) examine any effects that health literacy may have on the above factors. **METHODS:** This cross-sectional analysis used Medical Expenditure Panel Survey(MEPS) survey data from 2005 - 2008 and patients were identified using ICD-9 codes (733.xx) for osteoporosis. Patients' health literacy levels(HLL) were determined by using the health literacy scores(HLS), rated using the 2003 National Assessment of Adult Literacy to levels from basic or below basic(BBHLL<226) to above basic (ABHLL≥226) (range 0–500). The outcome variables were visits and costs as a function of HLL adjusted for other covariates. Adjusted logistic regression analyses determined factors that might influence HLL in osteoporotic patients. **RESULTS:** Majority of the total of 915 (20,486,934 weighted) individuals (mean age, 67.4; SD±11.7) were women (92%), Caucasians (91%) and on bisphosphonates (78%). The estimated national mean of HLS was 220.3(SD±27.5). Average annual visits and visits expenditure were 13.9 and $1,587 respectively. Individuals with ABHLL incurred less annual visits (13.4 vs 14.3) but paid more per visit ($130vs.$103) compared to those with BBHLL. Self-perceived health status(SPHS) was rated 2.35 times greater by ABHLL than those with BBHLL (OR:2.352,CI:1.43,-3.87). Patients with polypharmacy(>4 drugs) were 1.87 times less likely to have ABHLL($P<0.0001$) than those with BBHLL. **CONCLUSIONS:** Osteoporosis patients with ABHLL incurred less annual visits but paid more per visit. While increasing HLL may not decrease visits or expenditure per visit, it may decrease drug expenses, polypharmacy and improve SPHS, all associated with better health care outcomes.

PMS32

THE IMPACT OF PSYCHOLOGICAL TREATMENT OF RHEUMATIC PATIENTS WITH MENTAL HEALTH

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OBJECTIVES: To investigate the mental health of rheumatic diseases patients and explore the effect of psychotherapy for the mental health status in rheumatism inpatients. **METHODS:** 1. To compare the mental health status in rheumatism inpatients with normal by SCL-90 score. 2. 66 inpatients with rheumatism were recruited in the study and randomly divided into study group (n=33) and control group (n=33). The patients in the study group accepted psychotherapy and pharmacotherapy, and control group only accepted pharmacotherapy. 3. Six weeks later, the effect of psychotherapy to rheumatism inpatients were assessed by comparing the score of SCL-90 between the two groups. **RESULTS:** 1. The SCL-90 score significantly increased in rheumatism inpatients group compared with normal group: rheumatism inpatients group (152.8±35.9) and normal group (129.9±38.7), ($P<0.05$). 2. Six weeks later, the SCL-90 sore of study group was lower than that of control group. 3. The SCL-90 score significantly reduced after psychological treatment. **CONCLUSIONS:** The mental health status of rheumatism patients can not be ignored, because the patients have varying degrees of mental psychotic symptoms. The psychotherapy can improve the mental health status in rheumatism patients and can help the recovery of the patients.

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

PRS1

THE EFFECTIVENESS AND SAFETY OF FEBUXOSTAT : AN EXPERIENCE IN MEDICAL CENTER IN TAIWAN

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OBJECTIVES: The aim of this study was to assess the effectiveness and safety of febuxostat for chronic gout. **METHODS:** We retrospectively review patients with diagnosis of gout (ICD-9 250) concomitant with febuxostat during Jun 2012 to Dec 2013 in Changhua Christian Hospital. Patients with prescription of febuxostat less than 30 days were excluded. We collect the data of patient age, sex and analyzed the progression of renal function (eGFR) and uric acid. Prescribed Daily Dose (PDD) of febuxostat was calculated. Hospital-based spontaneous reporting systems databases were survey for the febuxostat adverse reaction reporting. **RESULTS:** A total of 151 patients were included with mean age 68.3±14.4 years. There were 40 female and 111 male (F:M ; 1:2.8). The average duration of prescription was 148.0±88.5 days. Prescribed Daily Dose (PDD) of febuxostat was 44mg. The uric acid was decrease from 9.1±1.9 to 6.6±2.7mg/dL. The eGFR was increased from 33.5±23.5 to 34.9±25.1 ml/min/1.73m^2. 86.7% (131) of patients with eGFR < 60 ml/min/1.73m^2 at the baseline. In subgroup analysis, 42 patients with the duration of prescription 31-90 days (average 55.8±15.6 days), 59 patients with 91-180 days(average 127.6±25.6 days), 50 patients with > 181 days (average 249.6±68.77 days), the uric acid derement was 2.3±2.8 mg/dL, 2.6±2.9 mg/dL and 2.8±2.1 mg/dL respectively. A total of 6 cases reported as mild adverse reaction, 4 cases reported as skin reaction. Other reactions reported was chills and insomnia. The incidence of ADR was 3.97%.(6/151). **CONCLUSIONS:** Febuxostat is an effective urate-lowering agent. We found a trend that the longer Febuxostat use, the more uric acid decline. The safety of febuxostat was well tolerated since the adverse reaction reported was mild. The total 6 cases adverse reaction reported were occurred in eGFR <60 ml/min/1.73m^2. Therefore, we need to closed monitor adverse reaction in CKD patients.

PRS2

INHALED ANTICHOLINERGICS AND RISK FOR ACUTE URINARY RETENTION: A CASE-CROSSOVER AND CASE-TIME-CONTROL STUDY

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OBJECTIVES: Recent nested case-control studies have raised concerns of the risk for acute urinary retention (AUR) among patients receiving tiotropium, a long-acting inhaled anticholinergic. In this study, we examined the effect of inhaled anticholinergics on the occurrence of AUR using self-controlled methods, case-crossover and case-time-control designs, which adjust for all time-invariant confounders and reduce threat of control-selection bias. **METHODS:** Patients aged ≥45 years with chronic obstructive pulmonary disease (COPD) were included from the IMS LifeLink Health Plan Claims Databases. Cases with AUR in both inpatient and outpatient settings during 2006-2009 were identified. In the case-time-control approach, ten controls were randomly selected for each case after matching age, gender, geographic location, to control for the secular trend of medication use. Exposure to tiotropium, ipratropium, and medications with significant anticholinergic effects was determined in the 30-day period prior to the event and in a 30-day reference period which was 180 days prior. Multivariate conditional logistic regression was used to evaluate the association between anticholinergic exposure and AUR, with sensitivity analyses and subgroup analyses based on age, gender and related comorbidities. **RESULTS:** A total of 6,008 cases and 60,080 controls were identified. The mean age was 74 years and ~78% were male. In the case-crossover analysis, adjusted odds ratio (OR) of AUR was 1.34 (95%CI 1.13-1.60) for tiotropium and 1.19 (1.00-1.41) for ipratropium. In the case-time-control analysis, the risk of AUR OR was 1.24 (1.03-1.50) for tiotropium and 1.26 (1.05-1.51) for ipratropium. The AUR risk related to tiotropium and ipratropium was similar among patients aged >75 years, males, and those with benign prostate hyperplasia, prostate cancer, and diabetes. **CONCLUSIONS:** Our results support current evidence that use of inhaled anticholinergics is associated with higher risk for AUR (odds increased by 20-35%) in COPD patients. Providers should be aware of the potential risk for AUR when making treatment decisions.

PRS3

COUGH AS A KEY SYMPTOM IN ASTHMA, ALLERGIC RHINITIS, COPD AND RHINOSINUSITIS AND ITS IMPACT IN ASIA

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